

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Robert E. Grove, et al.

Application No.: 10/783,603

Group Art Unit: 3735

Filed: February 19, 2004

Examiner: David M. Shay

Title: EYE SAFE DERMATOLOGIC TREATMENT

APPARATUS AND METHOD

Customer No.: 54412

Date: 26 February 2008

Supplemental Rule 132 Declaration of Dr. Gary C. Bjorklund

Gary C. Bjorklund declares and states as follows:

1. I am the Consulting Director at the Stanford Photonics Research Center at Stanford University. I am a past president of the Optical Society of America, a past president of the IEEE Lasers and Electro-Optics Society, and I am a Fellow of the Optical Society of America, the Institute of Electrical and Electronics Engineers, and the American Physical Society. I have authored over 100 technical publications, and I am an inventor on over 30 patents. I have served on the National Research Council Committee on Optical Science and Engineering, and I currently serve as the Chair of the Optical Society of America Foundation. I received my undergraduate degree in Physics from M.I.T. in 1968, and I received my Ph.D. in Applied Physics from Stanford University in 1974. My resume is attached hereto as Exhibit A.
2. I have no financial interest in the outcome of this matter, nor do I have any prior relationship with SpectraGenics or any of the inventors of the above-named patent application. I am being compensated for my time at my normal consulting rate.
3. I have reviewed the Office Action mailed 10/18/2007, including the portion thereof that refers to my prior declaration submitted in connection with this application. Essentially, the Examiner has disagreed with certain of my conclusions set forth in my earlier declaration. In particular, the Examiner asserts the following at page 3 of the Office Action:

('633) are erroneous. In paragraph 7, Declarant points to another passage concerning Figure 14, again stating that the light cannot be rendered eye safe with the arrangement therein. It is not clear that Declarant reviewed the actual figure this passage describes, however. The embodiment depicted clearly shows a stand off that allows the laser radiation to propagate until its cross section has increased to the point where the energy is at an eye safe level. The basis of Declarant's assertion that having an eye safe level is not possible, while having no idea whatsoever as to the cross section contemplated by Slatkine ('633), is far from clear, and thus the statements are not convincing. The discussion of Figure 14a at paragraph 8 suffers similar deficiencies. In paragraphs 9 and 10, Declarant discusses the diffusers of Figure 8b, however, Declarant does not discuss how the extended sources will be reimaged on the retina, given that the initial diffuser is composed of lenslets which "have a very short focal length of approximately a few wavelengths" (see page 32, lines 14-17). Thus these statements are not convincing. In view of the deficiencies of the statements enumerated above, the subsequent opinions set forth in paragraphs 11 through 17, which are predicated on the correctness of the statements preceding them, are not convincing. Similarly, the tables of results, which do not detail the precise types of diffusers, or, when detailed, make no effort to modify the designs to produce eye safe radiation, are not convincing of the lack of such teachings in Slatkine ('633).

4. I did review Figures 14 and B and the associated text prior to submitting my earlier declaration, and I have reviewed this material again. The conclusions set forth in my earlier declaration are correct. The Examiner misapprehends the teaching of Slatkine in relation to Figure 14A. The example given by Slatkine in the discussion of Figure 14A uses light with a wavelength in the range of 1400 nm to 13 microns. First, those skilled in this art recognize that the wavelength range given in Slatkine's example is not efficacious for hair removal because it is absorbed by the water in the skin before it can penetrate deeply enough to affect the hair follicles. Instead, light in the range of 600 nm to 1100 nm is typically used for hair removal, and wavelengths near 800 nm are most commonly preferred. Thus, Figure 14A is not, by its own terms, relevant to a device which is eye safe and effective for hair removal. If a laser source in the 800 nm range had been taught for this embodiment, the Maximum Permissible Exposure, as defined by the ANSI standard, would have been orders of magnitude lower. Or, stated differently, for wavelengths of light efficacious for hair removal, the stand off distance necessary to achieve eye safety in Slatkine's example would need to be, for a 10 joule light source, 790 cm for 1 msec pulses, and 240 cm for 100 msec pulses. These distances greatly exceed the length of the human arm. Further, at these distances, the light reaching the area of skin being treated would be of insufficient fluence to effect hair removal.

5. The FDA standard for eye safety for pulsed laser sources is not defined in terms of a "stand off", because of the risk that the device could inadvertently be triggered at a much closer distance. Thus, the standard distance used in the FDA standard is 10 cm. At a stand off of 10 cm, the device taught by Slatkine, if converted to a wavelength efficacious for hair removal, would be unsafe by several orders of magnitude.

6. The Examiner has also asserted that the discussion of the device shown in Figure 8B is not convincing because the discussion does not discuss how the extended sources will be reimaged on the retina. This criticism is misplaced, and reflects the Examiner's misunderstanding of the principals of optical physics involved here. It is not necessary, in determining eye safety, to model how each extended source taught by Slatkine is re-imaged on the retina. Instead, the correct approach is to calculate the integrated radiance of that source, which is what I did for the calculations submitted with my prior declaration. This point is made very clear by Sliney and Wolbarsht in their comprehensive handbook, Safety with Lasers and Other Optical Sources, Plenum Press, New York (1980), where at page 123, they state the following in connection with the formula (Equation 4-4) for calculating integrated radiance:

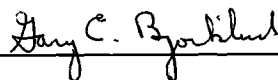
"Equation 4-4 is of great practical value, since it permits the definition of a permissible radiance (luminance) from a permissible retinal irradiance for any source of known radiance or luminance without concern for the viewing angle or viewing distance. Ignorance of this formula has caused many people to waste time trying to calculate with high precision the retinal image size of extended sources...."

It should be noted that the FDA standard also is based on integrated radiance. My calculations, included with my earlier declaration, use integrated radiance to establish that nowhere in Slatkine's teachings is there a device that is eye safe and of sufficient fluence to be effective for hair removal.

7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing therefrom.

Gary C. Bjorklund

Date: 26 Feb 2008

A handwritten signature in cursive script, reading "Gary C. Bjorklund", is written over a horizontal line.